United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Pesticide Data Program

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Title: Personnel and Organization		
Revision: 7	Replaces: 07/01/06	Effective: 07/01/08

1. Purpose:

To standardize the organization, operations, and personnel for those organizations participating in the collection of samples and performance of analytical determinations for the USDA/AMS Pesticide Data Program (PDP).

2. Scope:

This Standard Operating Procedure (SOP) shall be followed by USDA/AMS and all facilities involved in the collection of samples and performance of analytical determinations for PDP, including those laboratories which are conducting residue studies for PDP and support laboratories conducting stability or other types of studies which may impact the program.

3. Outline of Procedure:

5.1 Personnel Requirements
5.2 USDA/AMS-PDP Responsibilities
5.3 Program Administrative Director
5.4 Technical Director
5.5 Responsibilities of Participants
5.6 State/Facility Administrative Manager
5.7 State/Facility Sampling Manager
5.8 State/Facility Technical Program Manager
5.9 State/Facility Quality Assurance Unit (QAU)

4. References:

- USDA/AMS-PDP QA Committee Meeting, July 9-11, 1996
- USDA/AMS-PDP Technical Meeting, Minutes, February 13-15, 1996
- USDA/AMS-PDP Technical Meeting, Minutes, June 4, 1995
- USDA/AMS-PDP QA Committee Meeting, February 22-23, 1995
- USDA/AMS-PDP Technical Meeting, Minutes, March 2-3, 1993
- U.S. EPA, Inspection of a Testing Facility, 40 CFR part 160.15, August 17, 1989
- U.S. EPA, Personnel, 40 CFR part 160.29, August 17, 1989

- U.S. EPA, Testing Facility Management, 40 CFR part 160.31, August 17, 1989
- U.S. EPA, Study Director, 40 CFR part 160.33, August 17, 1989
- U.S. EPA, Quality Assurance Unit, 40 CFR part 160.35, August 17, 1989

5. Specific Procedures:

5.1 Personnel Requirements

5.1.a Each individual engaged in the conduct of or responsible for the supervision of the sample collection process or a PDP residue study shall have the education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

5.1.b Each participant shall maintain a current summary of training, experience, and job description for each individual engaged in the conduct of or responsible for the supervision of the sample collection process or a PDP residue study.

5.1.c Personnel engaged in a PDP study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent chemical contamination of samples and reference materials. Individuals shall take personal sanitary precautions necessary to avoid contamination of themselves, the samples, or reference materials.

5.1.d All personnel shall be instructed to report to their supervisors any existing health or medical conditions that may reasonably be considered to have an adverse effect on a PDP residue study.

5.2 USDA/AMS-PDP Responsibilities

5.2.a USDA/AMS has named the Monitoring Programs Office (MPO) Director as the PDP Program Administrative Director in charge of Financial and Administrative Affairs. Refer to section 5.3 of this SOP.

5.2.b The MPO Deputy Director has been designated as the Technical Director. Technical program reports shall be made to the Technical Director at USDA/AMS, 8609 Sudley Road, Suite 206, Manassas, VA 20110, (telephone (703) 330-2300 or FAX (703) 369-0678). Refer to section 5.4 of this SOP.

5.2.c USDA/AMS management shall:

5.2.c.1 Replace the Program Administrative Director or the Technical Director promptly if it becomes necessary to do so during the conduct of the PDP studies.

5.2.c.2 Ensure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.

5.2.c.3 Ensure that personnel clearly understand the functions they are to perform.

5.3 Program Administrative Director

USDA/AMS shall identify a scientist or other professional of appropriate education training and experience, or combination thereof, as the Program Administrative Director for PDP. The Program Administrative Director has the overall administrative responsibility for program expansion, budgeting, cooperative agreements, memoranda of understanding, and major disbursement of funds. The Program Administrative Director shall:

5.3.a Appoint and supervise a qualified individual to be responsible for and fulfill the duties of Technical Director.

5.3.b Inform the Deputy Administrator for USDA/AMS, Science and Technology, on financial and administrative affairs, as necessary.

5.3.c Prepare and submit annual budgets for the administration of PDP at the national level.

5.3.d Negotiate work contracts in cooperation with the States and/or other Federal agencies, after consultation with the Technical Director on the Statement of Work.

5.3.e Monitor through appropriate documentation the States' and/or Federal facilities' use of Federal funds.

5.3.f Serve as liaison to EPA, FDA, and other USDA agencies participating in PDP.

5.4 Technical Director

USDA/AMS shall identify a scientist of appropriate education training and experience, or combination thereof, as the Technical Director for PDP. The Technical Director shall:

5.4.a Serve as the major point of program control with responsibility for the sampling and technical conduct of the PDP residue study.

5.4.b Be responsible for overall monitoring of quality assurance of sampling, technical, and database operations to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with USDA/AMS program plans and SOPs.

5.4.c Ensure that data are reported in an annual program summary. This includes the interpretation, analysis, documentation, and reporting of results.

5.4.d Inform the Deputy Administrator for USDA/AMS, Science and Technology, and the Program Administrative Director on PDP sampling, laboratory, and database issues, as necessary.

5.4.e Serve as an additional liaison to EPA, FDA, and other USDA agencies participating in PDP.

5.4.f Consult with the Administrative Director on the Statement of Work during contract negotiations.

5.4.g Ensure that:

5.4.g.1 The program plan and PDP SOPs, including any changes, are approved and followed.

5.4.g.2 All sampling information and experimental data, including observations of unanticipated occurrences or responses, are accurately recorded and verified.

5.4.g.3 Unforeseen circumstances that may affect the quality and integrity of PDP samples and/or residue studies are documented as they occur, and corrective actions as necessary are taken and documented.

5.4.g.4 PDP sampling procedures and test systems are as specified in the program plan and SOPs. This shall be accomplished through reviews and frequent communications with participants.

5.4.g.5 Reviews of participant sampling and laboratory facilities are performed at intervals adequate to ensure the integrity of PDP samples and analytical results and written records of each review are maintained. The frequency of reviews for a particular participant shall be based on two factors:

5.4.g.5.a time elapsed since the last review, and/or

5.4.g.5.b designated need due to problems associated with the collection or analysis of samples performed by that participant. Participant Administrative Managers shall be notified and final arrangements shall be made at least two weeks in advance of the review when possible.

5.4.g.6 For sampling reviews, the review report is distributed to the participant's Administrative Manager and Sampling Manager, the USDA/AMS Administrative Director and Technical Director, and AMS Compliance and Analysis Programs. For laboratory reviews, the review report is distributed to the participant's Administrative Manager, Quality Assurance Officer, and Technical Program Manager; the USDA/AMS Administrative Director and Technical Director; and AMS Compliance and Analysis Programs.

5.4.g.7 The review reports are made available for inspection by authorized employees or duly designated representatives of USDA/AMS.

5.4.g.8 All raw data, documentation, protocols, SOPs, and final reports are transferred to the archives during or at the close of PDP.

5.5 Responsibilities of Participants

5.5.a Each participant shall designate an Administrative Manager. Each sample collection participant shall designate a Sampling Manager. Each laboratory participant shall designate a Technical Program Manager and a Quality Assurance Officer to lead the Quality Assurance Unit (QAU). Refer to sections 5.6, 5.7, 5.8, and 5.9 of this SOP.

5.5.b The participant management shall:

5.5.b.1 Replace the Administrative Manager, Sampling Manager, Quality Assurance Officer, or the Technical Program Manager promptly if it becomes necessary to do so during the conduct of the PDP study.

5.5.b.2 Ensure that there is a QAU as described in SOP PDP-ADMIN-06B.

5.5.b.3 Ensure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.

5.5.b.4 Ensure that personnel clearly understand the functions they are to perform.

5.5.b.5 Ensure that any deviations from the PDP SOPs, program policies, and approved analytical methodologies as reported by the QAU are communicated to the USDA/AMS Technical Director and that corrective actions are taken and documented.

5.5.b.6 Ensure an accurate and timely inventory of supplies and equipment purchased or utilized for PDP is maintained.

5.6 State/Facility Administrative Manager

Each participant shall identify a scientist or other professional of appropriate education, training, and experience, or combination thereof, as the Administrative Manager for PDP. The Administrative Manager has overall administrative responsibility for their organization's participation in PDP. This would include but not be limited to PDP activities such as: sampling operations, laboratory management, budgeting, contracting, purchasing, and receipt of QA reports and associated corrective actions. The State/facility Administrative Manager shall:

5.6.a Prepare and maintain annual budgets for PDP contract administration. For States/Facilities where budget functions are managed by person(s) other than the assigned Administrative Manager, a description of how laboratory costs are calculated (number of FTEs including salary and benefits, supplies, rent, utilities, etc.) shall be provided to the PDP Program Administrative Manager when requesting funding to cover PDP operations.

5.6.b In cooperation with USDA/AMS prepare and negotiate work contracts for PDP.

5.6.c Maintain appropriate accounting records to document the state/facility use of federal contract funding.

5.6.d Maintain appropriate performance records to document state/facility performance and productivity on PDP residue studies.

5.7 State/Facility Sampling Manager

Each sample collection participant shall identify a professional of appropriate education, training, and experience, or combination thereof, as the Sampling Manager for PDP. The Sampling Manager is responsible for the conduct of the participant's sampling procedures. The Sampling Manager shall ensure that:

5.7.a The PDP program plan and USDA/AMS SOPs, including any changes, are followed. Any problems regarding compliance with the program plan or SOPs shall be communicated immediately to the USDA/AMS Technical Director or designee.

5.7.b Participant internal SOPs are prepared documenting specific procedures utilized by the facility in collecting and shipping PDP samples. These SOPs are intended to serve as an attachment/appendix to USDA/AMS SOPs.

5.7.c The participant sampling plan and internal SOPs, including any changes, are followed.

5.7.d All required sampling information is accurately recorded and verified.

5.7.e Unforeseen circumstances that may affect the quality and integrity of PDP samples are documented as they occur, and corrective actions are taken and documented.

5.7.f Internal reviews of the procedures utilized by the sample collectors are performed at intervals adequate to ensure the integrity of PDP samples. The timeframe for performing internal reviews shall vary among participants based on the number of collectors to be reviewed. Each collector should be reviewed once before repeating the process. An exception would be if a number of problems are determined to be the result of a particular collector's negligence or failure to comply with the program SOPs.

5.7.g Group/individual training sessions are held periodically for the sample collectors. This is especially important if there are major program changes, or a number of sampling problems have been reported by either the USDA/AMS Technical Director or the applicable analytical laboratory(ies).

5.7.h Written and properly signed records of each review are maintained. Each review report shall show:

- the date of the review,
- the person(s) performing the review,
- observations, findings, and problems, recommendations and suggested corrective actions.

5.7.i The review reports are made available for inspection by authorized employees or duly designated representatives of USDA/AMS. Access to review reports should be limited to those individuals participating in PDP; however, storage under lock and key is not required.

5.7.j Any other documents required in the PDP Sampling SOPs shall be kept on file and updated as necessary (e.g., master site lists, FTE information, volume weighting information for collection sites, donation receipts, etc.)

5.8 State/Facility Technical Program Manager

Each participating laboratory shall identify a scientist or other professional of appropriate education training and experience, or combination thereof, as the Technical Program Manager for PDP. The Technical Program Manager has overall responsibility for the technical conduct of the PDP study contracted to the laboratory, as well as for the interpretation, analysis, documentation, and reporting of results. The Technical Program Manager shall ensure that:

5.8.a The PDP plan and all USDA/AMS SOPs, including any changes, are followed. Any problems regarding compliance with the program plan or SOPs shall be communicated immediately to the USDA/AMS Technical Director or designee.

5.8.b The laboratory plan, internal SOPs, and analytical methodologies, including any changes, are followed.

5.8.c All experimental data, including observations of unanticipated responses, are accurately recorded and verified.

5.8.d Unforeseen circumstances that may affect the quality and integrity of the PDP study are documented as they occur, and corrective action as necessary is taken and documented.

5.8.e All PDP test systems are as specified in the plan, SOPs, or analytical methods, including any approved changes.

5.8.f When requested, project status reports (e.g., progress on validation studies) are prepared.

5.8.g All required data is accurately transmitted electronically to USDA/AMS via remote data entry.

5.8.h All raw data, documentation, plans, SOPs, and final reports are transferred to the archives during or at the close of the PDP study.

5.9 State/Facility Quality Assurance Unit.

Each PDP participating laboratory shall have a QAU which shall be responsible for monitoring the PDP study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the plans and SOPs issued by USDA/AMS and by the laboratory.

The QAU shall be entirely separate from and independent of the personnel engaged in the technical direction and/or conduct of the study. The QAU shall report to non-technically involved laboratory management such as the laboratory director or the Administrative Manager. The Technical Program Manager is considered to be involved in the technical direction and conduct of the residue studies and therefore may not direct the QAU. Refer to USDA/AMS SOP PDP-ADMIN-06B for detailed duties.

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Revision 7 May 2008 Monitoring Programs Office

- General update

Revision 6

- Modified format to conform with other SOPs
- Changed responsibility for appointing a State/Facility Sampling Manager, Technical Program Manager, and Quality Assurance Officer from the State/Facility Administrative Manager to the participating State/Facility
- Changed responsibility for maintaining inventory from the State/Facility Administrative Manger to the participating State/Facility
- Added the Quality Assurance Officer to the laboratory review report distribution in subsection 5.4.g.6
- Added the Quality Assurance Officer to subsection 5.5.b.1
- Added requirement that if the State/Facility Administrative Manger is not responsible for budget functions, that the internal SOP describing how costs are calculated shall be provided to the PDP Administrative Program Manager to subsection 5.6.a
- Added subsection 5.7.j

Revision 5

- Modified format to conform with other SOPs
- Updated to conform with current Monitoring Programs Office organization